

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**IN RE VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION**

This Document Relates to:

MDL No. 2875

Honorable Robert B. Kugler,
District Judge

Honorable Thomas I. Vanaskie
Special Master

**IRBESARTAN AND LOSARTAN THIRD-PARTY PAYOR
PLAINTIFF'S FACT SHEET**

This Fact Sheet must be completed by each plaintiff who has filed a lawsuit claiming the right to recovery as a Third-Party Payor ("TPP") with respect to Losartan and/or Irbesartan products by covered insureds and/or members. Please answer every question to the best of your knowledge. In completing this Fact Sheet, you are under oath and must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details requested, please provide as much information as you can. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect. For each question, where the space provided does not allow for a complete answer, please attach additional sheets so that all answers are complete. When attaching additional sheets, clearly label to what question your answer pertains. Please do not leave any blank spaces; if a question does not apply, respond "N/A".

In filling out this form, please use the following definitions:

- (1) **"Document"** has the meaning set forth in Federal Rule of Civil Procedure 34;
- (2) **"Losartan"** means any Losartan-containing product, including but not limited to Losartan and/or Losartan/Hydrochlorothiazide (HCTZ);
- (3) **"Irbesartan"** means any Irbesartan-containing product, including but not limited to Irbesartan and/or Irbesartan/Hydrochlorothiazide (HCTZ);
- (4) **"ICD"** means any drug or combination drug containing **Irbesartan**
- (5) **"LCD"** means any drug or combination of drug containing **Losartan**.
- (6) **"Complaint"** means the operative complaint filed in your case, whether an original or amended or subsequent complaint;
- (7) **"Plan"** means any employee welfare benefit plan, whether or not in writing, whether or not governed by ERISA, FEHBA, contract, or any other statute, which was established or maintained for the purpose of providing covered individuals,

through the purchase of insurance or otherwise, prescription drug coverage medical, surgical, or hospital care, services, supplies or benefits in the event of sickness, accident, or injury;

- (8) **“Recipient”** means any person to whom services or products are or were provided under any Program, including covered insureds and Plan members;
- (9) **“Member ID”** means a unique ID number for Recipients which has been identified in accordance with the § 164.514(b) of the Health Insurance Portability and Accountability Act (“HIPAA”) Privacy Rule;
- (10) **“Program”** includes all health care policies, health care Contracts, health care Plans, or other health care insurance, employee health benefits, Medicaid, or other health care programs (including their predecessors) or health care expenditures for or with respect to which you seek damages or other relief in this action;
- (11) **“Damages”** means any form of monetary relief (irrespective of whether labeled as reimbursement, restitution, compensatory damages, punitive damages, or otherwise), and any other form of judicial relief;
- (12) **“Damages Period”** means January 1, 2011 to the date of the final recall of any LCD or ICD;
- (13) **“You,” “your,” “plaintiff,” “Third-Party Payor,”** and **“TPP”** shall be used interchangeably and refer to the plaintiff completing this Fact Sheet.
- (14) **“Claim”** (collectively, **“Claims”**) means the specific, individual transaction(s) regarding Your purchase(s) and/or coverage of and/or reimbursement for purchase(s) of ICDs and/or LCDs for which You seek any damages and/or equitable or legal relief of any kind from Defendants in this Litigation.
- (15) **“Insureds”** mean employees, employers, members, subscribers, policyholders, participants, beneficiaries, and/or insureds under the Plans and/or the Group Insurance Policies through which You [or, for MSPRC, any Assignor] provided some form of prescription drug coverage, payment, or reimbursement on which You [or, for MSPRC, any Assignor] base any allegation or request for damage in this Litigation.
- (16) **“Formulary”** means the formulary, preferred drug list, or other list of prescription drugs that are covered by the Plan(s) or Group Insurance Policies, including any tiers or levels of preference in which drugs are categorized.
- (17) **“Manufacturer Defendants”** means Zhejiang Huahai Pharmaceutical Co, Ltd., Princeton Pharmaceuticals Inc. d/b/a Solco Healthcare US LLC, Solco Healthcare US, LLC, Huahai U.S., Inc., Hetero Labs, Ltd., Hetero Drugs, Ltd., Hetero USA, Inc., Camber Pharmaceuticals, Inc., Teva Pharmaceutical Industries, Ltd., Teva

Pharmaceuticals USA, Inc., Vivimed Life Sciences Pvt Ltd., Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals Inc., Macleods Pharmaceutical Limited, Macleods Pharma USA, Inc., Torrent Pharmaceuticals, Ltd., Torrent Pharma, Inc., Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC.

- (18) **“Wholesaler Defendants”** means AmerisourceBergen Corporation (n/k/a Cencora, Inc.), McKesson Corporation, and Cardinal Health, Inc.
- (19) **“At-Issue Losartan and/or Irbesartan”** means those losartan and/or irbesartan drugs with a National Drug Code (NDC) associated with any of the Manufacturer Defendants identified in Plaintiffs’ Master Complaints and for which the Plaintiffs are seeking damages.

Information provided by plaintiff will only be used for purposes related to this litigation. This Fact Sheet is completed pursuant to the Federal Rules of Civil Procedure governing discovery (or, for state court cases, the governing rules of the state in which the case is pending) and Case Management Order No. __ (“CMO-__”), ECF No. __. Moreover, to the extent information in this Fact Sheet can be provided in native spreadsheet format as it is maintained, then plaintiffs may produce the information in that manner.

I. CORE CASE INFORMATION

- A. Each Third-Party Payor will provide information relating to payments for Losartan and/or Irbesartan products in the civil action(s) that they filed:

Caption(s):	
Court and Docket No. (and MDL Docket No. if different):	
Plaintiff's Attorney, Law Firm, Address, Phone Number, and Email Address:	
Date Lawsuit(s) Filed:	
Jurisdiction where suit(s) would have been filed (if direct filed into MDL):	
Basis for jurisdiction in venue where suit(s) would have been filed (if direct filed into MDL):	
Defendants against whom you are bringing claims relating to payments for Losartan:	
Defendants against whom you are bringing claims relating to payments for Irbesartan:	

II. ORGANIZATIONAL INFORMATION**A. Background Information**

1. Entity Name: _____
2. Names of your predecessor entities and those entities' date(s) of inception if you were the product of a merger, consolidation, or other reorganization, and state whether you seek Damages on behalf of such predecessor entities:

3. Location of your headquarters, place of incorporation, and your principal place of business (if different from headquarters):

B. Relevant Contractual Agreements

1. During the Damages Period, identify any Pharmacy Benefits Managers ("PBMs") with whom you had Contracts that covered the at issue Losartan and/or Irbesartan, and indicate which benefits years each entity served as your PBM:

3. During the Damages Period, did you have a contract(s) with any Manufacturer Defendants and/or Wholesaler Defendants related to the Losartan and/or Irbesartan products pursuant to which you made payments on behalf of Recipients for At-Issue Losartan and/or Irbesartan? **Yes** ☐ **No** ☐

If yes, identify the Manufacturer Defendants and/or Wholesaler Defendant(s) with whom you had a contract(s), identify the relevant time period associated

with each Contract(s), and describe the purpose of the Contract(s).

II. PROGRAM INFORMATION

A. Program Information

1. During the Damages Period, did you offer any Plans or Programs that involved a Medicare Advantage or Medicare Part D benefit and for which you paid for at issue Losartan and/or Irbesartan? **Yes** ☐ **No** ☐

If yes, produce the Contracts or agreements with the Centers for Medicare and Medicaid Services (“CMS”) under which such payments were made.

2. During the Damages Period, identify all Plans you offered pursuant to which you made payments on behalf of Recipients for At-Issue Losartan and/or Irbesartan, and provide the below information regarding each Plan:

Plan Name	Is the Plan a Medicare Advantage Plan or Medicare Part D Plan? If yes, provide CMS Contract ID	Years This Plan Was Offered		

B. Witnesses

1. Identify all persons with knowledge concerning the substance of your

allegations against the Defendants in this action.

Identify all persons who can testify about benefits and coverages afforded by, and rules, regulations, requirements, provisions and/or procedures governing, any Programs covering Losartan and/or Irbesartan products during the Damages Period.

Identify all persons who can testify about any policies, programs, procedures, and efforts utilized by you to identify and collect from other persons or sources amounts paid or incurred in connection with Programs covering Losartan and/or Irbesartan products during the Damages Period.

2. Identify all persons who were members of the Pharmacy & Therapeutics ("P&T") Committee or similar committee that made decisions about prescription drug coverage and formularies for at issue Losartan and/or Irbesartan offered by your Plans during the Damages Period.

C. Statements

1. Identify written or oral statements made by you and/or your agent(s) that reflect your opinions or views regarding at issue Losartan and/or Irbesartan products, or the Defendants' role related to such products, including, but not limited to, interviews, speeches, articles, advertisements, and any other form of public statement.

2. Identify all of your agents if any, who have participated in, or who have had responsibility for, the preparation of press releases, contacts with members of the press, broadcast or electronic media, social media, internet news outlets, the staging or conduct of press conferences or other activities to publicize or publicly comment upon your position regarding the at issue Losartan and/or Irbesartan products, or the Defendants' role related to those products.

D. Awareness of the Recall Condition

1. Describe with particularity when and how you became aware of the presence of nitrosamines in at issue Losartan and/or Irbesartan products.

IV. FRAUD CLAIMS

1. Are you claiming fraud or consumer fraud in this action on the basis of Plaintiff-specific allegations other than those set forth in the Master and Short Form Complaints?

Yes ☐ No ☐

If yes, please answer the following questions:

2. What representation(s) do you claim was falsely or fraudulently made and to whom was it made?

3. By whom?

4. How was it made?

5. When was the alleged representation(s) made? Identify approximate date(s).

6. Were these representations in writing? Yes ☐ No ☐
7. If the representations(s) was in writing, did you retain and currently have the original or a copy of those representations? Yes ☐ No ☐

V. DOCUMENT DEMANDS

- A. Please provide the following Documents, whether written or in electronic form, in the possession, custody or control, of you or your attorneys. Please indicate by answering “Responsive documents attached” or “I have no Documents responsive to this request” by checking/marking the appropriate box provided, and attach a copy of each of the Documents you have to this Fact Sheet with your responses to the questions above:

1. All non-privileged Documents you reviewed that assisted you in the preparation of the answers to this Fact Sheet.

Responsive documents attached ☐

I have no documents responsive to this request ☐

2. Detailed claims data showing all transactions for which you made payments on behalf of Recipients for at issue Losartan and/or Irbesartan, including but not limited to the following information, to the extent it exists:

- Prescription Benefit Plan Name or CMS Contract ID
- Member State
- Client Member ID
- Group IDClaim identifier
- Date of the Claim
- Date of purchase of the ICD/LCD made the subject of the Claim
- Date of Service
- Quantity dispensed
- Days’ Supply dispensed
- Patient Pay Amount
- Copay/Coinsurance Cost Tier
- Deductible Amount
- Net Check Amount
- Final Ingredient Cost Amount with regard to the ICD/LCD made the

- subject of the Claim
- Dispensing/Transaction Fee Amount with regard to the ICD/LCD made the subject of the Claim
- NDC Code of the ICD/LCD made the subject of the Claim
- Lot Number of the ICD/LCD made the subject of the Claim
- Drug Name of the ICD/LCD made the subject of the Claim
- Manufacturer of the ICD/LCD made the subject of the Claim
- Strength of the ICD/LCD made the subject of the Claim
- Dosage of the ICD/LCD made the subject of the Claim
- Pharmacy Name that dispensed the ICD/LCD made the subject of the Claim and the state in which that Pharmacy is located
- Mail Service RX that dispensed the ICD/LCD made the subject of the Claim
- Wholesaler Defendant(s) that distributed the ICD/LCD made the subject of the Claim
- The amount billed to You by the Wholesaler Defendant(s) with regard to the ICD/LCD made the subject of the Claim; and
- The amount paid by You to the Wholesaler Defendant(s) with regard to the ICD/LCD made the subject of the Claim;

The adjusted amount paid by You to the Wholesaler Defendant(s) with regard to the subject ICD/LCD made the subject of the Claim, including discounts, rebates, prescribing fees, PBM fees or other costs, allowances, or reimbursements; and

Responsive documents attached ☐

I have no documents responsive to this request ☐

3. For each Plan, policy, or prescription benefit product provided by you under which you paid amounts for at issue Losartan and/or Irbesartan, all summaries and/or Schedules of Benefits (and amendments thereto) and their substantive equivalents, for each benefit year in the Damages Period.

Responsive documents attached ☐

I have no documents responsive to this request ☐

4. For each Plan, policy, or prescription benefit product provided by you under which you paid amounts for at issue Losartan and/or Irbesartan, all formularies (and amendments thereto) and preferred drug lists for each benefit year in the Damages Period.

Responsive documents attached ☐

I have no documents responsive to this request ☐

5. All Documents sufficient to identify the procedures in medical insurance Programs during the Damages Period used to coordinate benefits with other potential payers, including procedures to verify that a beneficiary is not covered by any other

insurance policy, as well as the manuals or policy statements concerning such procedures, and all Documents concerning the effectiveness of those procedures.

Responsive documents attached ☐

I have no documents responsive to this request ☐

6. All Documents sufficient to identify the procedures in medical insurance Programs during the Damages Period, other than coordination of benefits procedures, used to identify and pursue other potentially liable parties, including the manuals, guidelines or policy statements concerning such procedures, and all Documents concerning the effectiveness of those procedures.

Responsive documents attached ☐

I have no documents responsive to this request ☐

7. All Documents that concern, explain, evaluate, criticize, or suggest improvements to the policies, programs, procedures, and efforts utilized during the Damages Period by you to identify and collect from persons or third-party resources amounts paid or incurred in connection with any medical insurance program.

Responsive documents attached ☐

I have no documents responsive to this request ☐

8. All Documents that concern your right (or lack thereof) to seek to recover from other persons or sources a portion of medical insurance program costs of providing services, including samples of all forms executed by applicants from time to time during the Damages Period assigning their rights of recovery or undertaking any duties, such as the duty to cooperate, with you.

Responsive documents attached ☐

I have no documents responsive to this request ☐

9. All Documents, databases, summaries, or compilations of data concerning a claim of contribution, indemnification, lien, subrogation, or other alleged right of recovery asserted by you against any person or entity concerning costs paid for Losartan and/or Irbesartan products or incurred during the Damages Period.

Responsive documents attached ☐

I have no documents responsive to this request ☐

10. All Documents in your possession which mention any alleged health risks related to or the recall of at issue Losartan and/or Irbesartan, or any alleged health risks or hazards related to those products, in your possession, other than legal Documents,

Documents provided by your attorney, or Documents obtained or created for the purpose of seeking legal advice or assistance.

Responsive documents attached ☐

I have no documents responsive to this request ☐

11. All Documents in your possession regarding the medications identified on the agreed list, attached as **Exhibit A**, purchased for your Recipients or for which you paid reimbursements after discovering the possible presence of nitrosamines in Losartan and/or Irbesartan medications. This Request includes, but is not limited to, all Documents identifying or discussing the price of such replacement medications and the cost incurred by you in purchasing such medications or in making reimbursement payments for the same, as well as detailed claims data pertaining to such transactions containing the information outlined in V.A.2 above.

Responsive documents attached ☐

I have no documents responsive to this request ☐

12. All Contracts between you and any Manufacturer Defendant, Wholesaler Defendant, and/or Pharmacy Benefit Manager identified in response to the preceding questions in section II.B.1 and II.B.2.

Responsive documents attached ☐ *I have no documents responsive to this request* ☐

13. All Documents in your possession or in the possession of anyone acting on your behalf (not your lawyer) obtained directly or indirectly from any of the Defendants relating to the recall of any Losartan and/or Irbesartan products.

Responsive documents attached ☐

I have no documents responsive to this request ☐

14. All Documents constituting any communications or correspondence between you and any representative of any of the Defendants relating to Losartan and/or Irbesartan products.

Responsive documents attached ☐

I have no documents responsive to this request ☐

15. All statements that were made or taken from any of the Defendants in this action, including, but not limited to, the current or former officers, directors, employees, or agents of any of the Defendants, concerning any of the claims alleged in this action.

Responsive documents attached ☐

I have no documents responsive to this request ☐

16. All public statements made by or on behalf of you relating to this litigation in your possession.

Responsive documents attached ☐

I have no documents responsive to this request ☐

17. All minutes or documents reflecting decisions made by the P&T Committee regarding formulary placement of at issue Losartan and/or Irbesartan, for the benefit years during the Damages Period.

Responsive documents attached ☐

I have no documents responsive to this request ☐

VI. DECLARATION

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that all of the information provided in this Plaintiff Fact Sheet dated ____ s true and correct to the best of my knowledge, information and belief formed after due diligence and reasonable inquiry, that I have supplied all the documents requested in Part V of this Plaintiff Fact Sheet, to the extent that such documents are in my possession or in the possession of my lawyers.

Further, I acknowledge that I have an obligation to supplement the above responses if I learn that they are in some material respects incomplete or incorrect.

Name of Plaintiff's Representative (Signature)

Date

Name of Plaintiff's Representative (Printed)

Title of Plaintiff's Representative